

# Laser Machining, Inc.

Providing Laser Solutions for Industry

June 18, 1999

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20850

Dear Sir or Madam:

RE: Intent to amend laser performance standard, docket no. 93N - 0044

The suggested amendments discussed in the March 24, 1999, Federal Register generally appear to be a welcome revision to CDRH requirements. The greater the effort toward harmonization with IEC/EN 60825-1 to achieve one world wide standard the greater the consistency of manufacture that can be achieved.


From the perspective of a high laser power industrial tool (cutting, welding, etc.) manufacturer, revising the CDRH standard to harmonize it with the IEC/EN standard will have very little effect on our products.

From a laser industry perspective I encourage the inclusion of the IEC amendment (76/CDV/196) in the proposed CDRH revision providing that amendment is adopted by the IEC.

The effort put forth to harmonize these standards is greatly appreciated.

If you believe that I can provide you with any additional input please feel free to contact me.

Sincerely,

  
Sherwood Johnston  
Manager, Regulations Compliance

Copy: Jerome Dennis  
Robert Weiner

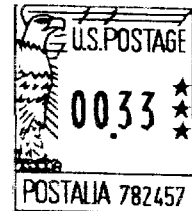
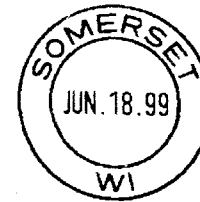
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